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Virginia Board of Pharmacy

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Board Calendar

The 2008 dates for the Virginia Board of Pharmacy full Board meetings were recently scheduled and are as follows: March 12, June 11, September 3, and December 10. Throughout the year, the Board calendar will be updated with newly scheduled dates for various committee meetings and any necessary scheduling changes. Please periodically check the Board calendar at *www.dhp.virginia.gov/pharmacy/pharmacy_calendar.htm* for the most up-to-date information and for access to meeting minutes.

Properly Accessing Will-Call

Dispensed prescriptions awaiting delivery, more commonly referred to as "will-call," may be stored and accessed for delivery to the patient in a few different ways. Frequently, the will-call is stored within the prescription department and is accessed when a pharmacist is on duty by a pharmacist, pharmacy technician, or a designated person performing clerical functions who has been authorized access to the prescription department by the pharmacist on duty. Alternatively, dispensed prescriptions awaiting delivery may be stored in a secure place outside the prescription department, ie, in a location where the public may not access the prescriptions, consistent with Board Regulation 18VAC110-20-200, *www.dhp.virginia.gov/Pharmacy/leg/Pharmacy_11292006.doc#_Toc153072921*. When stored outside of the prescription department, access to the prescriptions shall be restricted by the pharmacist to designated clerical assistants. Individuals who have not been designated by the pharmacist should not access the prescriptions. With the permission of the pharmacist, the prepared prescriptions may be transferred to the patient at a time when the pharmacist is not on duty. If a prescription is delivered at a time when the pharmacist is not on duty, written procedures shall be established and followed by the pharmacy that detail security of the dispensed prescriptions and a method of compliance with counseling requirements of §54.1-3319 of the Code of Virginia. Additionally, a log shall be made and maintained of all prescriptions delivered to a patient when a pharmacist is not present to include the patient's name, prescription number(s), date of delivery, and the signature of the person receiving the prescription. Such log shall be maintained for a period of one year.

A third method for accessing will-call is addressed in Board Regulation 18VAC110-20-190, *www.dhp.virginia.gov/Pharmacy/leg/Pharmacy_11292006.doc#_Toc153072920*. This regulation explains when and how a pharmacy technician accompanied by a member of the pharmacy's management or administration may access will-call stored within the prescription department at a time when there is no pharmacist on duty. This regulation, however, is very restrictive and may only be utilized at specific times.

Upon a request by a patient to obtain an already-dispensed prescription, a pharmacy technician may enter the pharmacy for the sole purpose of retrieving filled prescriptions that have already been reviewed and certified for accuracy by a pharmacist and deemed ready for delivery to the patient if all requirements of the regulation are met. Specifically, it should be noted that access may only be granted during a time of unforeseen, unplanned absence of a pharmacist scheduled to work during regular prescription department hours. Access may not be granted at a time when the prescription department is not routinely open, nor may access be granted in anticipation of a planned absence. Additionally, the pharmacy technician must be accompanied by a member of the pharmacy's management or administration and all aforementioned requirements of subsection A of 18VAC110-20-200 must be followed. It should also be noted that the pharmacy technician must obtain verbal permission from the pharmacist-in-charge (PIC) or another pharmacist regularly employed by that pharmacy to enter the prescription department and to use the emergency key or other access and alarm access code. Permission may not be given by a district manager or pharmacy supervisor who does not regularly work in the affected prescription department. Once the prescription department is accessed, the accompanied pharmacy technician may only retrieve filled prescriptions that have already been reviewed and certified for accuracy by a pharmacist and deemed ready for delivery to patients, and then exit. The pharmacy technician may not remain in the prescription department or perform any prescription processing functions such as processing refills, preparing labels, counting drugs, etc. These processing functions may only be performed at a time when a pharmacist is on duty. After exiting the prescription department, a record shall be made by the pharmacy technician of the entry consistent with 18VAC110-20-190 E.3 and shall be maintained on the premises for a period of one year. Lastly, the pharmacy technician shall reseal the key and alarm access code after the pharmacy is resecured, and the PIC shall have the alarm access code changed within 48 hours of such an entry and shall document that this has been accomplished on the record of entry.

DEA Finalizes Rule on Issuance of Multiple Prescriptions

Final regulations allowing the issuance of multiple prescriptions for Schedule II controlled substances (CS) became effective

Continued on page 4

NABP Testifies in Support of Proposed BTC Drug Class

NABP testified at the Food and Drug Administration (FDA) meeting November 14, 2007, stating its support for the proposed creation of a behind-the-counter (BTC) class of drugs. The meeting was held to solicit input on the public health benefits of certain medications being available BTC without a prescription but only after intervention by a pharmacist.

A long-time advocate of this measure, NABP passed a resolution in 1993 advocating a third class of drugs that would be dispensed without a prescription only by licensed health care professionals authorized to prescribe and/or dispense prescription drugs. Continuing its support of this concept, NABP passed a resolution in 1995 stating that medications being converted from prescription-only to over-the-counter status that pose serious risks and require patient education for effective use should be placed in a special class requiring sale only by licensed health care professionals after counseling the patients on proper use.

More information is available in the *Federal Register* (Docket No. 2007N-0356).

A Rose by Any Other Name . . . Might Be Safer

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to ***ISMP Medication Safety Alert!® Community/Ambulatory Edition*** *by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

What's in a name? Well, if the name is referring to a pharmaceutical compound getting ready to go to market, a lot goes into that name.

In order for a drug manufacturer to test its drug chemicals in animals, it must submit three possible generic names to the United States Adopted Names (USAN) Council, the organization responsible for assigning generic drug names. USAN Council selects a generic drug name, based on safety, consistency, and logic and then refers this name to the World Health Organization to check for similar generic names being used in other countries.

There is a method to this naming madness. For instance, drug name "stems" group therapeutically-related drugs. An example would be the stem *-vastatin* for drugs that lower cholesterol, and is used in the generic names of atorvastatin (Lipitor®) and lovastatin (Mevacor®). Another example of the use of stems is *-mab* used in anticancer drugs. MAB stands for 'monoclonal antibodies' and is used in the generic drugs names alemtuzumab and cetuximab. The stem gives clues about what a drug is used for; however, drug names that share a common stem can contribute to medication errors because they may sound or look alike. This is especially problematic if the products share common dosage forms and other similarities.

Additionally, USAN Council guidelines call for generic names to be simple to pronounce with only one way to say it and have no more than four syllables. Yet, the names mentioned in the preceding paragraph are difficult to pronounce and some have five syllables.

After a drug has completed phase-I clinical trials, the manufacturer submits potential brand names to FDA as well as the US Patent and Trademark Office.

Drug manufacturers often work with drug naming companies to help them develop unique brand names. A report in the January-February 2004 issue of the *Journal of the American Pharmacists Association* stated that there are more than 9,000 generic drug names and 33,000 trademarked brand names in use in the US. Although the drug names may be unique, more and more often they are leading to miscommunications and are resulting in errors.

According to USP-ISMP Medication Errors Reporting Program (MERP) data, 25% of the errors reported relate to the products generic or brand name. To help combat this problem, in 1990 FDA established the Labeling and Nomenclature Committee (LNC) to review proposed trade names. The LCN, which has evolved into the Division of Medication Errors and Technical Support of the Office of Surveillance and Epidemiology, formerly the Office of Drug Safety, has been actively reviewing drug names.

Although prescribers and consumers would like drug names to give an indication of the intent of the drug in the name itself, FDA prohibits trade names associated with the product's intended use and will not approve names that imply efficacy. Yet there are many exceptions to this "intended" rule. A drug such as Celebrex® (pain treatment) connotes "celebration" and Halcion® (sleep aid) conjures up images of restfulness (halcyon). Perhaps naming drugs for their intended purpose would decrease the number of medication errors associated with confusing and sound-alike/look-alike drugs. Until prescribers conform to writing the indication or purpose on the actual prescription, the drug name itself may give a clue to the patient as to what is being prescribed. The patient may read the prescription before handing it to the pharmacist and question why he or she is being prescribed "Oncocure" when he or she does not have cancer.

Studies estimate that anywhere from 7,000 to 20,000 people die or are injured each year in the United States because of drug name confusion. What can pharmacists do? Go to the Med-E.R.R.S.® Web site *www.med-errs.com* and register to become a drug name reviewer. Although not required, many drug companies seek the consultant advice of Med-E.R.R.S. to test their potential generic and brand names before submitting these names to FDA. Med-E.R.R.S., Inc, a wholly owned subsidiary of ISMP, assists pharmaceutical and health care technology companies in evaluating the safety of their products and services. Med-E.R.R.S., Inc has tested more than 600 names for over 35 pharmaceutical companies in 2006. Med-E.R.R.S. integrates knowledge and experience with the input of clinicians in the field to systematically analyze potential trademarks, packaging, and technology.

Med-E.R.R.S. pharmacist reviewers participate in online surveys to review names of potential drugs handwritten by a number of "prescribers" to determine if any of the tested names look like medical terms or other current drugs on the market. They are also asked to review the potential drug names to compare if the potential name sounds like another drug or like another medical term.

To further national efforts to manage drug name confusion, ISMP hosted an invitational summit on October 9-10, 2007, in Philadelphia. This meeting brought together a full range of pharmacy professionals

and representatives from standard-setting organizations, regulatory agencies, the pharmaceutical industry, and the payer community. During the meeting, the attendees discussed post-marketing strategies to identify and reduce name confusion and ways to improve upon their scope and effectiveness. ISMP believes that the health care industry can significantly reduce the risk to patients from otherwise preventable product mix-ups due to look-alike and sound-alike names. A report from the summit will be available online soon.

So a rose by any other name may smell as sweet, but Reminyl® renamed Razadyne™, (see ***ISMP Medication Safety Alert!® Community/Ambulatory Edition***, Volume 4, issue 5, May 2005, **Reminyl®/ Amaryl® Your Reports at Work.**) may "smell" safer, and therefore "sweeter." Sweeter, that is until recently when MERP started receiving errors involving confusion between Razadyne and Rozerem™. Stay tuned.

FDA Study Suggests Consumers are Seeking Meds Online to Avoid Rx Rules

FDA recently announced the results of a year-long investigation, which suggest that consumers are buying drugs online to avoid the need for prescriptions from their physicians.

The investigation, comprising surveys conducted from September 2006 to August 2007 in international mail and courier facilities across the country, found 88% of the 2,069 drug packages examined appeared to be prescription medicines available in the US. More than half (53%) of the products sampled have FDA-approved generic versions, likely sold at lower costs, according to earlier studies that have shown generics in the US to be generally less expensive than comparable drugs in Canada or Western Europe. Other products included dietary supplements, foreign products with "illegible or incomprehensible" labeling, and medications not available in the US.

FDA warns that products from unregulated Internet drug sellers may contain the wrong ingredients or toxic substances. Earlier this year, FDA learned that 24 apparently related Web sites operating outside the US may be involved in the distribution of counterfeit prescription drugs.

FDA Posts Drug Safety Newsletter, Labeling Changes

FDA released the first issue of its new *Drug Safety Newsletter* in late 2007. The quarterly online newsletter provides information for health care professionals about the findings of selected post-marketing drug safety reviews, emerging drug safety issues, and recently approved new drugs.

The newsletter is available on the FDA Web site at *www.fda.gov/cder/dsn/default.htm* and will be sent electronically to *Drug Safety Newsletter* and/or MedWatch subscribers.

FDA also provides monthly updates on medication labeling changes, such as boxed warnings, contraindications, warnings, precautions, adverse reactions, and patient package insert/medication guide sections. The Safety-Related Drug Labeling Changes page is accessible at *www.fda.gov/medwatch/safety.htm.*

NABP Awards DMEPOS Accreditations Representing Over 11,000 Pharmacies

NABP accredited several independent pharmacies and chains, representing over 11,000 pharmacies, through its durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation program during fourth quarter 2007.

The DMEPOS program ensures that pharmacies supplying DMEPOS products meet the Centers for Medicare and Medicaid Services' (CMS) quality and accreditation standards. Those pharmacies that are accredited through the program are doing their part to ensure that Medicare beneficiaries receive the appropriate products, services, and patient care associated with DMEPOS.

A full listing of pharmacies accredited through the NABP DMEPOS program is available under Accreditation Programs on the NABP Web site, *www.nabp.net.*

FDA Acts to Ensure Thyroid Drug Potency until Expiration

FDA is tightening the potency specifications for levothyroxine sodium to ensure the medication retains its potency over its entire shelf life. FDA is taking this action in response to concerns that the potency of the drug may deteriorate prior to its expiration date.

The revised potency specifications require levothyroxine sodium drug products to maintain 95% to 105% potency until their expiration date. Previously, these products were allowed a potency range of 90% to 110%. FDA has given manufacturers and marketers two years to comply with the revised specification.

More information is available on the FDA Web site at *www.fda.gov/cder/drug/infopage/levothyroxine/default.htm.*

FDA Reform Law Provides for Establishment of Tracking Standards

President Bush signed HR 3580, the Food and Drug Administration Amendments Act of 2007, into law on September 27, 2007. Among other provisions, the law reauthorizes and expands the Prescription Drug User Fee Act and the Medical Device User Fee and Modernization Act.

The legislation expands FDA authority to regulate marketed drugs, establish a surveillance system to monitor and assess the safety profile of drugs on the market, reauthorize and modify programs that evaluate the use of drugs and devices by children, and expand federal databases that track information on certain clinical trials.

The law also requires the US Department of Health and Human Services to establish a standardized numerical identifier that must be applied to prescription medications at the point of manufacture, and to develop standards to serve as guidelines in the implementation of track-and-trace and package-level identification technology to monitor prescription medications through the supply chain.

2008 Survey of Pharmacy Law Now Available

The NABP 2008 *Survey of Pharmacy Law* CD-ROM is now available. The *Survey* consists of four sections including organizational law, licensing law, drug law, and census data. New topics include whether or not states recognize Verified Internet Pharmacy Practice Sites™ accreditation and if the boards of pharmacy require compliance with United States Pharmacopeia Chapter 797, "Pharmaceutical Compounding – Sterile Preparations."

To order the *Survey,* visit *www.nabp.net* and download an order form; the cost is $20.

The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from Purdue Pharma LP. For more information on the *Survey,* please contact NABP via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

Continued from page 1

December 19, 2007. The regulation allows practitioners to provide individual patients with multiple prescriptions, to be filled sequentially, for the same Schedule II CS, with such multiple prescriptions having the combined effect of allowing a patient to receive over time up to a 90-day supply of that CS. It specifically requires the prescriber to provide written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each subsequent prescription. Additionally, Drug Enforcement Administration (DEA) clarified that it does not intend to mandate or encourage prescribers to issue multiple prescriptions or to dictate how often prescribers should see their patients when prescribing Schedule II CS. The rule also does not limit the quantity of a Schedule II CS that may be prescribed on a single prescription when multiple prescriptions are not issued at the same time. Rather, DEA stated that each prescriber must exercise sound medical judgment in determining whether it is appropriate to issue multiple prescriptions and how often the patient should be seen.

Please note that there is nothing in Virginia law or regulation to prohibit a prescriber from issuing multiple prescriptions for a Schedule II CS consistent with the aforementioned federal regulation. Additionally, there is nothing in Virginia law or regulation to prohibit a pharmacist in Virginia from dispensing multiple prescriptions for Schedule II CS that comply with the federal ruling. For more information click on *www.deadiversion.usdoj.gov/fed_regs/rules/2007/fr1119.htm.*

Pain Management Course Now Offered

The Prescription Monitoring Program has partnered with the School of Medicine at the Virginia Commonwealth University (VCU) in the development of an online pain management curriculum called VCU Chronic Nonmalignant Pain Management. This curriculum emphasizes current issues in the management of pain through a case-based format and offers ongoing access to practice resources in pain management. Registration for the program is free of charge, and the Virginia Board of Pharmacy has approved three hours of continuing education credit for completion of this program. This is not an Accreditation Council for Pharmacy Education-approved program and therefore may not be accepted as continuing education in other states or for purposes of Pharmacy Technician Certification Board recertification. When registering for the program, please input a Virginia pharmacist license number or pharmacy technician registration number, along with the case-sensitive access code: "Virginia Pain." The program is located on the Prescription Monitoring Program's Web site at *www.dhp.virginia.gov/dhp_programs/pmp/default.asp.*

Prescription Monitoring Program Update

The Prescription Monitoring Program finished 2007 by fulfilling 22,156 requests compared to 6,333 requests in 2006. Prescribers, as in most states, made the greatest number of requests for dispensing history information at 72%, followed by pharmacists at 13%, the Virginia State Police at 7%, the Department of Health Professions at 3%, the Virginia Medical Examiner's Office at 3%, the Health Practitioners' Intervention Program at 1%, and DEA made 1% of requests. There are now over 19.6 million records in the program database, with pharmacies submitting almost one million records each month. Going forward into 2008, the program will look to expand service to 24/7 access and "automatic response." Information regarding these changes will be included in future e-newsletters.

USP Releases Chapter 797 Revision

Revisions to the United States Pharmacopeia (USP) General Chapter 797, "Pharmaceutical Compounding – Sterile Preparations" will become official on June 1, 2008. The current version of Chapter 797 in *The United States Pharmacopeia,* 31st Revision and *The National Formulary,* 26th Edition *(USP – NF),* remains the official text until June 1, 2008. At that time, the revised chapter will be published in Second Supplement to USP 31 – NF 26, and in the Pharmacists' Pharmacopeia. The new chapter is not identical to the proposed revision published in May 2006. For more information concerning the newly revised Chapter 797 and training opportunities offered by USP, please click on *www.usp.org/USPNF/pf/generalChapter797.html.*

Currently, §54.1-3410.2 of the Drug Control Act requires pharmacies performing sterile or nonsterile compounding to comply with USP standards. In the past, however, the Board recognized that some pharmacies were not currently compliant with the new physical requirements of Chapter 797, and the Board, also, acknowledged the time and costs associated with making the necessary capital improvements to facilities in order to comply with the new requirements. Additionally, it was well known that USP was in the process of revising Chapter 797. Therefore, the Board decided to create guidance document 110-36, which granted all pharmacies engaged in sterile compounding time to make the necessary physical improvements. The document explains that the Board currently expects pharmacies to comply with the "old" standard of performing sterile compounding in at least a Class 100 (ISO 5) environment, in addition to complying with all required policies and procedures, training and evaluation of personnel, and other requirements of Chapter 797 at the time of inspection. The guidance document concludes that the Board expects all pharmacies engaged in sterile compounding to be in full compliance with Chapter 797, to include all physical requirements, by June 30, 2008. Although, the newly finalized USP Chapter 797 will become official on June 1, 2008, the Board will continue to honor the deadline of June 30, 2008, as stated in guidance document 110-36 found at *www.dhp.virginia.gov/Pharmacy/guidelines/110-36%20Compliance%20with%20USP%20Chapter%20797-June%202006.doc.*

Drop Boxes Approved for Pharmacies

The Board adopted a guidance document on December 12, 2007, which allows a pharmacy to utilize a drop box for the collection of written prescriptions and refill requests. The drop box must be located in a visible area within the permitted facility and must be locked at all times with access to the items placed in the drop box restricted to pharmacists practicing at the pharmacy or an authorized pharmacy technician practicing at the pharmacy when a pharmacist is on duty. The drop box shall be constructed in a manner to prevent the theft or loss of a written prescription or confidential information and shall be bolted to the floor or a fixed structure. At no time shall a patient be allowed to leave containers that contain drugs to be refilled. For a complete listing of guidance documents, click on *www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm*.

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